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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,615	03/11/2002	William R. Fitz	FIT-10202/29	4947

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EXAMINER

LAYNO, CARL HERNANDZ

ART UNIT PAPER NUMBER

3762

DATE MAILED: 05/10/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/018,615

Applicant(s)

FITZ, WILLIAM R.

Examiner

Carl H. Layno 5/5/04

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 March 2002.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☒ Claim(s) 13-27 is/are allowed.  
6) ☒ Claim(s) 1-3 and 8-12 is/are rejected.  
7) ☒ Claim(s) 4-7 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 11 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Acknowledgment is made of applicant's preliminary amendment which was received by the Office on March 11, 2002. This document has been made of record in the file as Paper No.6.
2. Claims 1-27 are active and pending.

***Priority***

3. Acknowledgment is made of applicant's claim for priority as a national stage 371 application as disclosed in the applicant's pre-amendment (Paper No.6) to PCT/US00/00544, filed January 10, 2000, and to priority filing based upon applicant's own U.S Patents 6,014,588 (filed April 7, 1998) and 6,314,325 (filed June 18, 1999).

***Oath/Declaration***

4. Acknowledgment is made of the receipt of applicant's new declaration, which was received by the Office on March 11, 2002. This paper has been filed in the case as Paper No.4.

***Drawings***

5. Applicant's formal drawings were received by the Office on March 11, 2002 and have been approved by both the Draftsperson and the Examiner.

***Double Patenting***

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6. Claims 1-3 and 8-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 4-8, respectively, of U.S. Patent No. 6,314,325-B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because all features recited by the applicant's claims are set forth in those of the '325-B1 patent. In fact claims 2, 3, and 7-12 were copied verbatim.

7. Claims 8-10 and 12 are also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-5 and 7, respectively of U.S. Patent No. 6,014,588. Although the conflicting claims are not identical, they are not patentably distinct from each other because all of the method steps broadly recited by the applicant's claims are more specifically set forth in the '588 patent. Claims 9 and 10 appear to have been copied verbatim.

***Allowable Subject Matter***

8. Claims 4-7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Claims 13-27 are allowed.

10. The following is a statement of reasons for the indication of allowable subject matter:

Art Unit: 3762

Independent claim 13 recites the details of an apparatus for relieving pain having a controller which generates a series of positive electrical pulses of “sufficient electrical intensity to cause hyperpolarization of the nerve”, yet not strong enough to affect the spinal cord. The Examiner could not find this and other of applicant’s claimed features in the prior art..

Independent claims 14 and 25 recite methods for treating pain and vascular disorders using a neural stimulator by performing the unique steps of placing one of the stimulator’s positive electrodes near a patient’s peripheral or sciatic nerve and placing the stimulator’s negative electrode at a separate remote region of low sensitivity (i.e. among adipose tissue) some distance away from the positive electrode. Although the concept of treating pain using electrical stimulation of the sciatic nerve is old and well known in the art (e.g. Avery et al ‘368), none of the prior art references teaches separating the negative electrode from the positive in the manner claimed by the applicant. On the contrary, the prior art teaches the use of multipolar leads whose positive and negative electrodes appear to be co-located on the same leads (e.g. King ‘331 and Weiner ‘075-B1). It is also unclear from the prior art references whether or not the energy delivered by their stimulating devices is adequate to hyperpolarize the peripheral or sciatic nerves, as claimed by the applicant. In view of these shortcomings, the Examiner deems independent claims 14 and 25, and their depending claims to be allowable over the prior art of record.

### ***Conclusion***

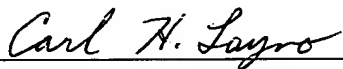
11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Feler et al '964 and Alo et al '957 patents are cited for their pertinent teachings regarding nerve root stimulators. Unfortunately, these references could not be used due to their defective filing dates.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every other Friday between 9AM and 5PM. A voice mail or E-mail message ([carl.layno@uspto.gov](mailto:carl.layno@uspto.gov)) may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (703) 308-5181. All faxed correspondence should be sent to the Office's new Official FAX number (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (703) 305-7520.



CARL LAYNO  
PRIMARY EXAMINER

CHL  
5/5/2004